MEDICAL DEVICES AGENCY
DIRECTIVES BULLETIN

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COMPLIANCE COST ASSESSMENTS

INTRODUCTION

This information bulletin is the 14th in a series explains in broad terms the outcome of the Compliance Cost Assessments (CCAs) for the Active Implantable Medical Devices and Medical Devices Directives and a preliminary assessment for the proposed In Vitro Diagnostic Medical Devices Directive. These are the three Directives regulating medical devices throughout the European Community which started to come into effect in the UK from January 1993.

The CCAs were undertaken by the Department of Health's Medical Devices Agency in close consultation with the medical device industry and its Trade Associations.

WHAT IS A CCA?

A CCA is a structured appraisal that all Government Departments must prepare and publish when evaluating policy proposals likely to affect business. As part of its deregulation initiative the UK Government requires that all new EC legislation is accompanied by a CCA. Its purpose is to inform Government Ministers and officials of the likely costs to business of complying with new or amended regulations. When preparing a CCA, industry, trade associations and in particular representatives of small businesses are consulted about the likely direct compliance costs and other regulatory impacts. It is recognised that a careful balance has to be maintained between risk, costs and benefits.

WHAT DOES A CCA CONTAIN?

The principal components of a CCA are estimates of the recurring and non recurring costs to business. Recurring costs are additional and indirect costs arising from the proposed Directive or regulation, such as extra staff, "opportunity costs" (ie the cost of existing staff who might otherwise be used more profitably), consumable materials, periodic inspection and licence fees.

Non recurring costs are one-off costs such as additional expenditure on plant and machinery, buildings, infrastructure and computer systems.

CCA FOR ACTIVE IMPLANTABLE MEDICAL DEVICES (AIMD) DIRECTIVE

Most businesses covered by the implementing Regulations for the AIMD Directive are internationally based. However, their distributors were included in this CCA to establish the cost implications on their businesses. The compliance cost was identified as any additional costs incurred in putting into place administrative and quality assurance procedures to meet the requirements of the Directive, and the on-going cost. The Medical Devices Agency sent questionnaires to approximately 90% of UK AIMD manufacturers and distributors. A total of 18 companies and three trade associations were consulted. UK distributors did not perceive that the Regulations placed a significant cost burden on them directly although 45% of the industry anticipated the need for a price rise with 5% quoted as the highest figure. This means a cost to industry of £0.6M and to the NHS of £0.4M. It is expected that the cost will affect mainly the internationally based company. The figures are based on 1993 prices.

CCA FOR MEDICAL DEVICES DIRECTIVE (MDD)

COSTS TO BUSINESS

During the course of determining the likely impact of impending UK legislation, questionnaires were sent to 220 UK companies involved in the manufacture and/or distribution of medical devices. The CCA established that costs will have to be met as a result of procedural changes in administration, quality systems and conformity assessment required for compliance, as well as changes in product design, manufacture, labelling, packaging and documentation. The outcome of the consultation with industry indicates an initial gross cost to industry estimated at £100 million and to the NHS at £30 million as a result of expected price increases. The recurrent annual gross compliance cost is estimated to be about £50 million and the benefit to the UK industry is expected to be about £12 million in respect of the decrease in barriers to trade.

COST TO THE NHS OF IN-HOUSE MANUFACTURE

Some hospitals manufacture certain devices "in-house" and place them on the market, so these activities will be covered by the regulations. A partial survey of relevant NHS activities showed that at least 270 hospital departments and at least 100 sterile services departments could be affected by the Directive. The hospital departments include medical physics/bioengineering departments, wheelchair centres, hearing aid insert and orthotics/artificial limb centres. A conservative estimate for the compliance cost is of the order of £3.5 millon for those hospital departments affected, excluding sterile services departments. These costs would reduce to approximately £1.8 million if it was considered that the scope of the Directive excluded certain activities that remain within a single hospital.

CCA FOR PROPOSED IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVD) DIRECTIVE

To help the Medical Devices Agency compile a CCA, a questionnaire was sent to 240 companies/organisations. Most companies in the IVD industry are small in size usually employing less than 20 staff and over 40% have gross sales of under £1 million. The results of the CCA indicate that compliance with the proposed IVD Directive will have an approximate cost to the UK industry of £10 million gross initially. The recurrent annual gross compliance cost is estimated to be approximately £3.6 million. The result of consequential price increases to the consumer (principally the NHS) is likely to attract a cost of approximately £4 million per annum initially. Costs will be incurred through the need for manufacturers to put in place effective quality systems. For manufacturers of certain high risk products and for self testing IVDs, intervention by a third party certification body (Notified Body) might be necessary.

There will also be a direct compliance cost to the NHS (as yet unquantified) because some manufacturing activities carried out by hospitals may be regarded as "placing on the market" as defined in the proposed Directive.

UK manufacturers exporting devices to those European countries with existing relevant premarket national regulations will gain some benefit by having to follow only one conformity assessment route. The benefit to UK industry is expected to be approximately £350,000 per annum.

PUBLISHED CCAS

CCAs are published documents. They will be issued free to manufacturers and Trade Associations who participate in their preparation. CCAs will be available to all others at the following prices:

Active Implantable Medical Devices Directive
(18) pages - £15 (Cost of handling, postage and packaging)

In Vitro Diagnostic Devices Directive
(24) pages - £15 (Cost of handling, postage and packaging)

Medical Devices Directive (not available until January 1995)
(52) pages - £50 (Price includes handling, postage and packaging).

If you would like a copy of any of the CCAs mentioned in this Bulletin please send your request together with a cheque for the amount (made payable to Medical Devices Agency) to:

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Corporate Finance
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FURTHER INFORMATION

For copies of earlier Bulletins in our series, and, if required, further information about the Directives, please contact:

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